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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/452,658	05/25/1995	WALTER C. FIERS	B8/B8-CIP-DI	5499
7590	10/31/2007		EXAMINER	
JAMES F HALEY JR FISH AND NEAVE 1251 AVENUE OF THE AMERICAS NEW YORK, NY 100201104			MARTINELL, JAMES	
ART UNIT	PAPER NUMBER			
	1634			
MAIL DATE	DELIVERY MODE			
10/31/2007	PAPER			

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	08/452,658	FIERS, WALTER C.
	<b>Examiner</b>	<b>Art Unit</b>
	James Martinell	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 31, 33, and 34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08).  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

The application has been remanded from the Board of Patent Appeals and Interferences (see the Office communication mailed August 15, 2007).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 31 and 34 are rejected under 35 U.S.C. § 102(g) as being clearly anticipated by either one of Sugano et al (U.S. Patent No. 5,514,567) or Sugano et al (U.S. Patent No. 5,326,859). Each of the Sugano et al patents discloses a DNA that encodes the same amino acid sequence as is recited in claim 34 of the instant application (e.g., see Table 5 at columns 11-12 in each of the references). Additionally the DNA in Table 5 of each of the Sugano et al references would hybridize to the DNAs mentioned in claim 31 of the instant application because the DNA in Table 5 of each of the Sugano et al references differs by only one nucleotide (at codon 30) from the DNA recited in claim 33 of the instant application) and also encodes a beta-interferon. Thus, the DNA of Sugano et al is embraced by claim 31, parts 1) (a) and 1) (b) of the claim. The use of beta-interferon to stimulate the immune system in the treatment of human cancers and for viral diseases is disclosed in each of the Sugano et al references at column 1, lines 10-30) and the expression of DNA encoding beta-interferon in heterologous non-human hosts is taught in Sugano et al '567 at column 15 and claims 21-31 and in Sugano et al '859 at column 16. Thus, the methods taught in each of the Sugano et al references are embraced by claims 31 and 34 of the instant application. The U.S. Court of Appeals for the Federal Circuit concluded (*Fiers v. Sugano*, 25 USPQ2d 1601, U.S. Court of Appeals for the Federal Circuit, decided January 19, 1993),

that Sugano is entitled to rely on his disclosure as enabling since it sets for the a detailed teaching of a method for obtaining a DNA coding for  $\beta$ -IF and the Board did not err in determining that Fiers presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for  $\beta$ -IF . . . . The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of section 112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

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Appellant's arguments (brief, pages 4-6) are not convincing. Appellant complains that there is no evidence of record to indicate that Sugano et al had completed an actual reduction to practice of the invention in this country prior to appellant's effective U.S. filing date. The instant application and the two Sugano et al patents disclose the same amount of information relevant to the methods claimed in the instant application. Appellants have not disagreed with this fact. Since the Court of Appeals for the Federal Circuit has already determined that Sugano et al are entitled to priority (Fiers v. Sugano, 25 USPQ2d 1601, Fed. Cir. 1993) for what is for interference purposes a patentably indistinct invention, the rejection under 35 U.S.C. § 102(g) is made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail.

Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

#### **OFFICIAL FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1634**

10/25/07